



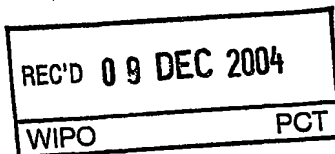
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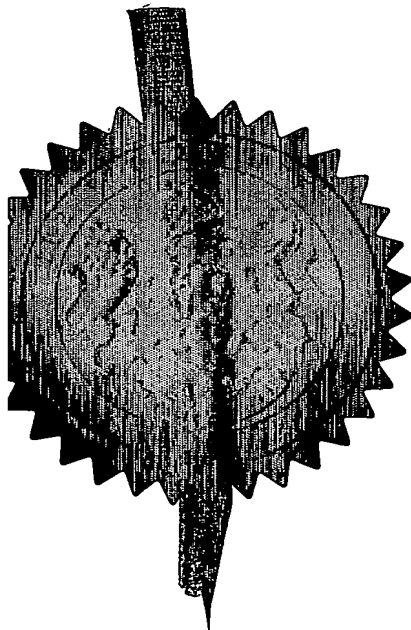


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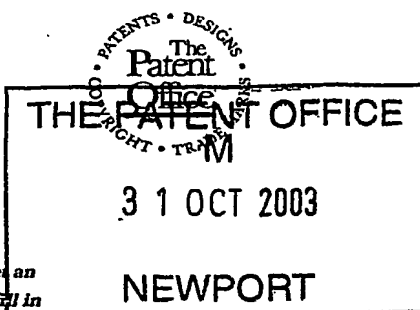
*Stephen Hordley*

Dated

30 November 2004

# Patents Form 1/77

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1. Your reference

P34789-/CMU/RTH/RMC

2. Patent application number

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0325442.2

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Mpathy Medical Devices Limited  
6.05 Kelvin Campus  
West of Scotland Science Park  
Glasgow  
G20 0SP

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

08730905001

United Kingdom

4. Title of the invention

"Plug"

5. Name of your agent (if you have one)

Murgitroyd & Company

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Scotland House  
165-169 Scotland Street  
Glasgow  
G5 8PL

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1198043

1198015

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number  
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Date of filing  
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

Yes

- a) any applicant named in part 3 is not an inventor, or
  - b) there is an inventor who is not named as an applicant, or
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## Patents Form 1/77

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Description

17

Claim(s)

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Abstract

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Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

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11. I/We request the grant of a patent on the basis of this application.

Signature *Murgitroyd & Company* Date 30 October 2003  
Murgitroyd & Company

12. Name and daytime telephone number of person to contact in the United Kingdom ROISIN MCNALLY 0141 307 8400

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1 "Plug"

2

3 The present invention relates to a device for  
4 bodily hernia repair, particularly, but not  
5 exclusively, to a plug device for inguinal hernia  
6 repair or femoral hernia repair.

7

8 Hernias are due to an abnormal protrusion of an  
9 organ or part thereof through its containing  
10 structure, due to a rupture or weakening in a layer  
11 of fascia creating an aperture or a defect in the  
12 fascia which causes it to be less able to contain  
13 the organ or part thereof.

14

15 Hernias can occur at various anatomical positions in  
16 the abdomen where there is a weakness in the muscle,  
17 and are classified according to the site in which  
18 they occur.

19

20 Two particular types of hernia are inguinal hernias  
21 and femoral hernias.

22

1 Inguinal hernias occur in the groin when a portion  
2 of bladder, bowel or membrane pushes through a weak  
3 spot in the abdominal musculature around or at the  
4 inguinal canal. The inguinal canal is an opening  
5 between layers of abdominal muscle near the groin  
6 through which the spermatic cord passes in the male.  
7 Typically, inguinal hernia is a male condition.

8  
9 Two particular types of inguinal hernias occur,  
10 direct inguinal hernias and indirect inguinal  
11 hernias.

12  
13 An indirect inguinal hernia passes through the  
14 internal ring of the inguinal canal, along the canal  
15 and, if the hernia is large enough, emerges through  
16 the external ring and in the male descends into the  
17 scrotum.

18  
19 A direct inguinal hernia differs from an indirect  
20 inguinal hernia as it pushes its way directly  
21 forwards through the posterior wall of the inguinal  
22 canal. Occasionally, in unusual circumstances, a  
23 direct hernia becomes large enough to push its way  
24 through the external ring and then into the neck of  
25 the scrotum.

26  
27 The femoral artery and vein enter the femoral  
28 triangle from beneath the inguinal ligament within a  
29 fascial tube termed the femoral sheath. The femoral  
30 canal is a small, almost vertically-placed gap in  
31 the medial part of the femoral sheath. The femoral  
32 canal is a potential point of weakness in the

1 abdominal wall which may develop a femoral hernia.  
2 The canal is around 1 to 1.5 cm in length. As the  
3 female pelvis is of greater width than the male  
4 pelvis the femoral canal can be somewhat larger in  
5 females and female femoral hernias are more common.  
6 A femoral hernia is a protrusion through the femoral  
7 canal. The hernia sac may extend through the  
8 femoral canal.

9  
10 Hernia repair generally requires the contents of the  
11 hernia to be eased back into position and then for  
12 the weakened area to be repaired. Repair can be  
13 effected by tension or tension-free suturing of the  
14 tissue and muscle to strengthen the weakened area or  
15 occlude ruptured areas. Alternatively the weakened  
16 or ruptured area can be reinforced using a portion  
17 of synthetic mesh.

18  
19 Meshes for use in the treatment of an inguinal or  
20 femoral hernia typically consist of a flat portion  
21 of mesh for application over the hernia area. The  
22 mesh allows a tension free repair to be made of the  
23 weakened area.

24  
25 Alternatively for a well circumscribed defect, e.g.  
26 a deep inguinal hernia or femoral hernia, the repair  
27 device may be a plug which stops the rupture hole of  
28 the hernia.

29  
30 Plug devices of the prior art include the Bard  
31 PERFIX plug <sup>TM</sup>, Ethicon's Prolene Hernia System <sup>TM</sup>,  
32 and Surgipro Hernia Mate plug and Patch <sup>TM</sup> or Atrium

1 Self-forming plugs <sup>TM</sup>. The Bard PERFIX plug <sup>TM</sup> is one  
2 of the most popular plugs and comprises around 8  
3 leaves or petals, which are joined in a central  
4 region. The central portion of the plug is pushed  
5 into the defect and the leaves trimmed according to  
6 the size of the defect such that they stop the  
7 defect. As the leaves project from the central  
8 portion these aid the retention of the plug in the  
9 defect. In addition, an overlay patch may be  
10 positioned over the plug which surrounds those  
11 tissues surrounding the inguinal canal. Surgipro  
12 Hernia Mate plug and Patch <sup>TM</sup> and Atrium Self-  
13 forming plugs <sup>TM</sup> also comprise several leaves and an  
14 overlay patch and work in a similar fashion to the  
15 Bard product.

16  
17 Ethicon's Prolene Hernia System <sup>TM</sup> comprises a first  
18 overlay patch for placing around the inner ring of  
19 the inguinal canal a central portion and a second  
20 overlay patch for placing around the outer ring of  
21 the inguinal canal. The central portion corresponds  
22 to both a portion of the first and second overlay  
23 patches such that it is held in the inguinal canal  
24 by the two patches to block the canal.

25  
26 In use, the plugs of the prior art block the  
27 inguinal canal and prevent a hernia sac from  
28 protruding through the canal. The defects blocked  
29 by the plugs are substantially circular in cross  
30 section. However, anatomical structures which under  
31 normal circumstances pass through the inguinal  
32 canal, such as the spermatic cord, protrude at the

1 edge of the plug. In conventional plugs these  
2 anatomical structures are compressed between the  
3 plug and the surrounding tissue. This can lead to  
4 discomfort for the patient and might lead to long  
5 term damage to the structure(s) being compressed and  
6 may cause ischaemia of a distal organ, for example  
7 where the anatomical structure includes the  
8 spermatic cord ischaemia of the testes may occur as  
9 a result of compression of the artery and/or vein  
10 along with the spermatic cord.

11  
12 According to the present invention there is provided  
13 a prosthesis for hernia defect occlusion comprising  
14 a plug having at least an outer surface and an inner  
15 surface wherein, in a side of the plug, the inner  
16 surface forms a channel through which, in use, an  
17 anatomical structure may pass when the plug is in  
18 place in the body without substantial compression of  
19 said anatomical structure.

20  
21 An advantage of a prosthesis of the present  
22 invention is that by providing such a passage in the  
23 prosthesis, damage and discomfort caused by  
24 compression of anatomical structures passing through  
25 the defect being repaired can be minimised, while  
26 minimising the rupture or protrusion of a hernia sac  
27 through the defect/canal, such as the inguinal or  
28 femoral canal.

29  
30 Preferably the prosthesis has a truncated conical  
31 shape. Preferably the inner surface defines a  
32 scalloped channel.



1

2 A prosthesis of truncated conical shape in which a  
3 first end of the prosthesis has a diameter less than  
4 that of a second end has the advantage that the  
5 prosthesis can be pushed first end into the  
6 defect/canal, to plug the defect/canal, more easily.

7

8 It is preferable that the channel has a  
9 substantially semi-circular edge in cross section,  
10 such that the inner surface is substantially curved  
11 as it interfaces with the anatomical structure which  
12 the channel receives. However, it will be  
13 understood that the edge of the channel may include  
14 at least one straight portion such that the inner  
15 surface has a straight portion in cross section, for  
16 example a box section channel.

17

18 Preferably the prosthesis is formed from resilient  
19 material such that the prosthesis can be flexed to  
20 open the access to the channel.

21

22 This is advantageous in that the channel may be  
23 formed such that, in use, the prosthesis may be  
24 flexed from its rest position to an open position to  
25 increase the width of the access to the channel  
26 enabling the anatomical structure to be more easily  
27 received by the channel and then the prosthesis may  
28 be released to return to the rest position wherein  
29 the anatomical structure is substantially enclosed  
30 by the channel when the prosthesis is located in the  
31 defect.

32

1 In certain preferred embodiments the channel is  
2 capable of receiving a spermatic cord.

3

4 In alternative embodiments, the channel is capable  
5 of receiving a femoral vein, or other anatomical  
6 structures.

7

8 Preferably the channel is sized such that, in use,  
9 the anatomical structure which passes through the  
10 channel is not substantially compressed. In one  
11 embodiment, substantial compression of the  
12 anatomical structure is compression which causes  
13 pain to the patient or ischaemia of a distal organ.  
14 Preferably the width of the anatomical structure,  
15 which in use passes through the channel, is  
16 compressed less than 70%, even more preferably less  
17 than 50%, yet preferably less than 40%, even more  
18 preferably less than 30%, even more preferably less  
19 than 20%, yet more preferably less than 10%, even  
20 more preferably less than 5%, even more preferably  
21 less than 3%, most preferably less than 1% by the  
22 channel of the plug.

23

24 As prior art devices are pushed into the aperture,  
25 and can trap an anatomical structure between the  
26 exterior of the prior art device and the tissue  
27 surrounding the aperture, a significant pressure may  
28 be experienced by an anatomical structure.

29 Significant pressure is pressure which causes  
30 distortion, compression or full or partial collapse  
31 of an anatomical structure. For example, in  
32 particular examples where a conventional plug is

1 used to treat inguinal hernia, the spermatic cord is  
2 squeezed between the plug and the tissues  
3 surrounding the aperture and this squeezing may  
4 cause pain or even damage to the spermatic cord.

5  
6 Preferably the level of compression experienced by  
7 the anatomical structure by the prosthesis of the  
8 present invention when the anatomical structure  
9 passes through the channel of the prosthesis is not  
10 more than venous pressure. Venous pressure is  
11 typically between 2 to 10 mm Hg.

12  
13 Preferably the prosthesis has a single channel. In  
14 another embodiment the prosthesis can include two  
15 channels. Each channel may be sized to receive at  
16 least one anatomical structure in order to maximise  
17 the support provided by the prosthesis while  
18 allowing the structure(s) to pass through the one or  
19 more defined channels in the prosthesis.

20  
21 In particular embodiments the prosthesis may  
22 comprise a plurality of channels on its surface.  
23 The provision of a plurality of channels may be  
24 advantageous as different anatomical structures may  
25 be received by the prosthesis at different points  
26 around the surface of the prosthesis.

27  
28 In a preferred embodiment of the present invention  
29 the prosthesis comprises a flange provided on either  
30 one or both ends of the prosthesis. The provision  
31 of a flange on the prosthesis is advantageous as it  
32 aids location of the prosthesis in the body and may

1 provide additional support to tissue surrounding the  
2 defect. In particular embodiments, the flange is  
3 mounted on the prosthesis such that, in use, the  
4 flange provides an inferomedial extension to the  
5 prosthesis. For example, if the prosthesis is used  
6 to plug an inguinal canal, one end of the prosthesis  
7 is positioned at the internal inguinal ring of the  
8 inguinal canal and a second end is positioned at the  
9 external ring of the inguinal canal and a flange can  
10 inferomedially extend from the external ring.

11

12 Preferably the flange is a portion of synthetic  
13 mesh.

14

15 This is advantageous as a flange constructed of mesh  
16 has minimal mass density in relation to its volume.

17

18 The flange portion may contain structures or regions  
19 capable of receiving sutures or other fixing means  
20 to secure the flange around the anatomical  
21 structures received by the channel and/or to the  
22 surrounding tissue.

23

24 Preferably the prosthesis is constructed of mesh,  
25 solid material, foam or hydrogel. In particular  
26 embodiments the prosthesis is formed from rolls of  
27 mesh and/or comprises cross members to provide the  
28 prosthesis with strength to resist compression. In  
29 particular embodiments the mesh or solid material  
30 may be formed from plastics material. In particular  
31 embodiments the foam is formed from polyurethane.

32

1 In preferred embodiments the prosthesis has a  
2 crenated outer surface. The crenated surface allows  
3 the prosthesis to grip the tissues surrounding the  
4 prosthesis and aids retention of the prosthesis in  
5 position.

6  
7 Preferably the prosthesis has a longitudinal length  
8 or depth of between 1 to 5 cm. More preferably the  
9 prosthesis has a longitudinal length in the range of  
10 between 2 to 3 cm.

11  
12 In embodiments wherein the plug has a truncated  
13 conical shape the diameter of the widest end of the  
14 prosthesis is preferably between 2 to 7 cm and the  
15 diameter of the narrowest end is preferably between  
16 0.5 to 4 cm.

17  
18 The channel receiving the anatomical structure can  
19 have any suitable cross sectional shape such as a  
20 semi-circular cross section. Preferably the channel  
21 is between 0.5 cm to 3 cm in width and depth or  
22 where the channel is of circular or substantially  
23 circular cross section, for example semi-circular  
24 cross section, the channel is between 0.5 cm to 3 cm  
25 in diameter.

26  
27 Embodiments of the present invention will now be  
28 discussed, by way of example only, with reference to  
29 the accompanying figures in which;

30

31 Figure 1 shows a perspective view of an  
32 embodiment of a prosthesis of the invention

1 from one end;

2

3 Figure 2 shows a perspective view of an  
4 embodiment of a prosthesis of the invention  
5 from the other end;

6

7 Figure 3 shows a perspective view of an  
8 embodiment of a prosthesis of the invention in  
9 use;

10

11 Figure 4 shows an indirect inguinal hernia;

12

13 Figure 5 shows a hernia repaired using a device  
14 of the prior art;

15

16 Figure 6 shows an embodiment of a prosthesis  
17 which further includes a flange provided at one  
18 end of the prosthesis of the invention;

19

20 Figure 7 shows an illustration of the anatomy  
21 around the inguinal canal; and

22

23 Figure 8 shows an illustration of the anatomy  
24 around the femoral canal.

25

26 The prosthesis has application to plug or stop any  
27 aperture in the body in which a structure is  
28 required to pass through or adjacent to the  
29 aperture. For example, the prosthesis can be used  
30 to plug the inguinal canal or the femoral canal.

31

32 As shown in figure 1, in one embodiment, the

1 prosthesis 10 is a truncated cone of mesh material  
2 wherein the inner surface is defined by a  
3 substantially scalloped portion 12 formed by an open  
4 edged cylindrical (scalloped) channel 13 removed  
5 from the outer conical surface of the cone such that  
6 a prosthesis 10 of crescent cross section is  
7 provided.

8  
9 As shown in figures 1 and 2 the prosthesis has a  
10 first end 14 which, in use to plug an inguinal  
11 canal, is positioned at the internal inguinal ring  
12 of the inguinal canal. In use, the second end 16 is  
13 positioned at the external ring of the inguinal  
14 canal.

15  
16 The prosthesis has a channel 12 in the outer conical  
17 surface of the prosthesis capable of receiving an  
18 anatomical structure(s) which passes through the  
19 inguinal canal. The channel is in the range of 5 mm  
20 to 20 mm in width. Although in the embodiment shown  
21 in figures 1 to 3, the channel is substantially  
22 semi-circular in cross section, the channel may be  
23 of any shape. In addition, more than one channel  
24 may be present in the conical surface of the  
25 prosthesis, each channel being able to receive a  
26 particular anatomical structure.

27  
28 Typically the prosthesis is between 1 to 5 cm in  
29 length between the ends and around 1 to 4 cm in  
30 diameter.

31  
32 As shown in figure 3, in use, an anatomical

1 structure 30 is received by the channel 12, the  
2 channel indenting the conical surface of the  
3 prosthesis, the channel linking the ends 14,16.

4  
5 In use the prosthesis of the present application can  
6 be pushed into the inguinal canal to contain the  
7 organs or parts being pushed through the inguinal  
8 canal and to minimise their protrusion through the  
9 inguinal canal.

10  
11 In contrast to the devices of the prior art,  
12 anatomical structures, such as the spermatic cord,  
13 can be received by the channel 12 of the prosthesis  
14 such that such anatomical structures can pass from  
15 one end of the prosthesis to the other with minimal  
16 compression by the prosthesis.

17  
18 As shown in figure 5, previous plugs to stop the  
19 inguinal canal have utilised plug devices which are  
20 pushed into the canal, but which do not have means  
21 to allow the passage of structures such as the  
22 spermatic cord through or around the plug. This  
23 means the anatomical structure, such as the  
24 spermatic cord, is therefore compressed between the  
25 plug and the surrounding tissue, which can lead to  
26 patient discomfort and potentially may damage the  
27 anatomical structure.

28  
29 The prosthesis of the present invention may further  
30 comprise a flange or lip which protrudes laterally  
31 from the second end to aid the positioning of the  
32 device in the inguinal canal. The lip may be formed



1 from mesh and extend from the prosthesis such that  
2 in use the mesh can be used to support the  
3 musculature surrounding the inguinal canal. Thus in  
4 particular embodiments the prosthesis can include an  
5 inferomedial mesh extension. This allows the device  
6 of the present Application to be used in the  
7 treatment of direct inguinal hernias. A prosthesis  
8 of the present application may further include a  
9 flange 18 at the first end of the prosthesis. The  
10 prosthesis can be positioned into the inguinal canal  
11 and the flange used to support the tissue  
12 surrounding the canal.

13

14 As shown in figure 6, such a flange 18 or lip may  
15 comprise mesh material which extends laterally from  
16 the second end. In use, the tissue or fascia  
17 surrounding the inguinal canal can be supported  
18 using the mesh. It can be appreciated that the  
19 flange can be designed or cut to an appropriate size  
20 for either locating the prosthesis in the canal or  
21 to support surrounding tissue.

22

23 In a further embodiment a flange is provided on both  
24 ends of the prosthesis. In such an embodiment, if  
25 the flange is formed from a mesh material, the mesh  
26 can be provided around the internal ring and  
27 external ring of the inguinal canal such that the  
28 tissue and fascia around the inguinal ring is  
29 sandwiched between two layers of mesh. This  
30 supports the tissue and/or fascia and minimises the  
31 likelihood of organs or structures rupturing or  
32 protruding through the tissue and/or fascia.

1  
2 Although figure 6 shows the flange extending away  
3 from the spermatic cord, the flange may extend in  
4 all directions from either end of the prosthesis.  
5 Where the flange extends in all directions, the  
6 flange may include a cut portion and aperture to  
7 enable the flange portion to be arranged around the  
8 anatomical structure such as the spermatic cord  
9 received by the channel.

10  
11 In addition, the flange portion may contain  
12 structures or regions capable of receiving sutures  
13 or other fixing means to secure the flange around  
14 the anatomical structures received by the channel  
15 and/or to the surrounding tissue.

16  
17 To aid the fixation of the prosthesis in the  
18 inguinal canal the prosthesis may be crenated on its  
19 exterior surface. Such crenations will project from  
20 the surface of the prosthesis into the surrounding  
21 tissue and minimise the movement of the prosthesis  
22 once it has been suitably positioned.

23  
24 As shown in figure 8, the femoral canal, which is  
25 about 1 cm in length is located in the medial part  
26 of the femoral sheath. As discussed above, the  
27 femoral canal is a point of potential weakness in  
28 the abdominal wall through which a hernia may  
29 develop. A prosthesis of the present application can  
30 be inserted into the femoral canal to minimise the  
31 protrusion of the hernia sac through the femoral

1 canal while allowing the passage of anatomical  
2 structures through or into the prosthesis.

3

4 The function of the femoral canal is to firstly act  
5 as a dead space for expansion of the distended  
6 femoral vein and secondly as a lymphatic pathway  
7 from the lower limb to the external iliac nodes.

8

9 The channel of the prosthesis of the present  
10 application can be orientated such that expansion of  
11 the femoral vein is into the channel of the  
12 prosthesis and thus in contrast to plugs of the  
13 prior art, compression of the expanded vein against  
14 the side of the prosthesis will be minimised. In  
15 addition, the channel will still provide for  
16 movement in the lymphatic system from a lower limb  
17 to external iliac nodes. In one embodiment a  
18 prosthesis for use in plugging the femoral canal of  
19 the present invention is substantially of triangular  
20 prism shape. In another embodiment, in cross  
21 section, the prosthesis is substantially arrowhead  
22 shaped having two outer arcuate sides which extend  
23 from a base towards each other to form a point.  
24 Preferably the point is rounded. Alternatively the  
25 prosthesis is substantially D shaped with the  
26 arcuate sides forming a more rounded arched point.  
27 The base portion is preferably indented towards the  
28 point to receive an anatomical structure.

29

30 As discussed above, the prosthesis may further  
31 include a flange at either or both ends, which can  
32 extend around the femoral canal and thus support the

1 surrounding tissue or fascia. Such a flange may  
2 also contain cutouts to accommodate structures such  
3 as the femoral nerve and / or artery.

4

5 The prosthesis of the present application has been  
6 designed to take into consideration the anatomical  
7 structures and properties of the inguinal and  
8 femoral canal to minimise the disruption of these  
9 structures following location of the prosthesis.

10

11 Various modifications can be made without departing  
12 from the scope of the invention, for example,  
13 flanges extending from the faces of the prosthesis,  
14 as discussed above, may be formed from material with  
15 memory, such that following placement in the body  
16 the flanges move from a collapsed position to an  
17 extended position to secure the prosthesis in the  
18 body.

1/6

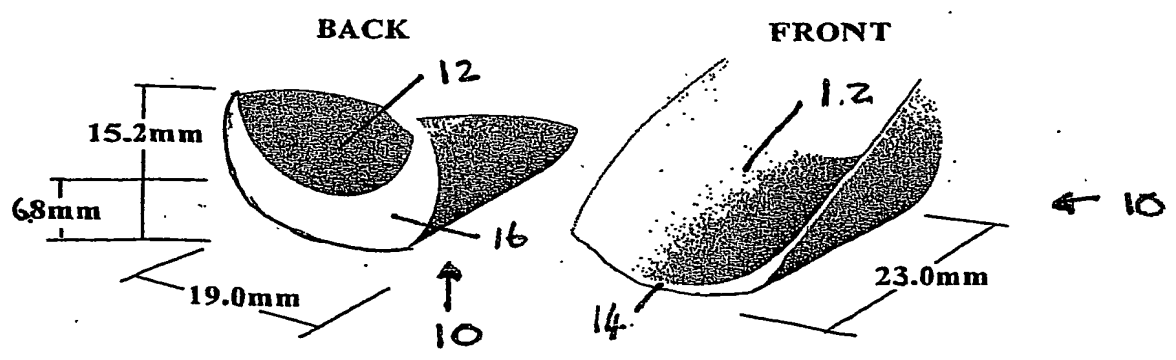


Figure 1

Figure 2

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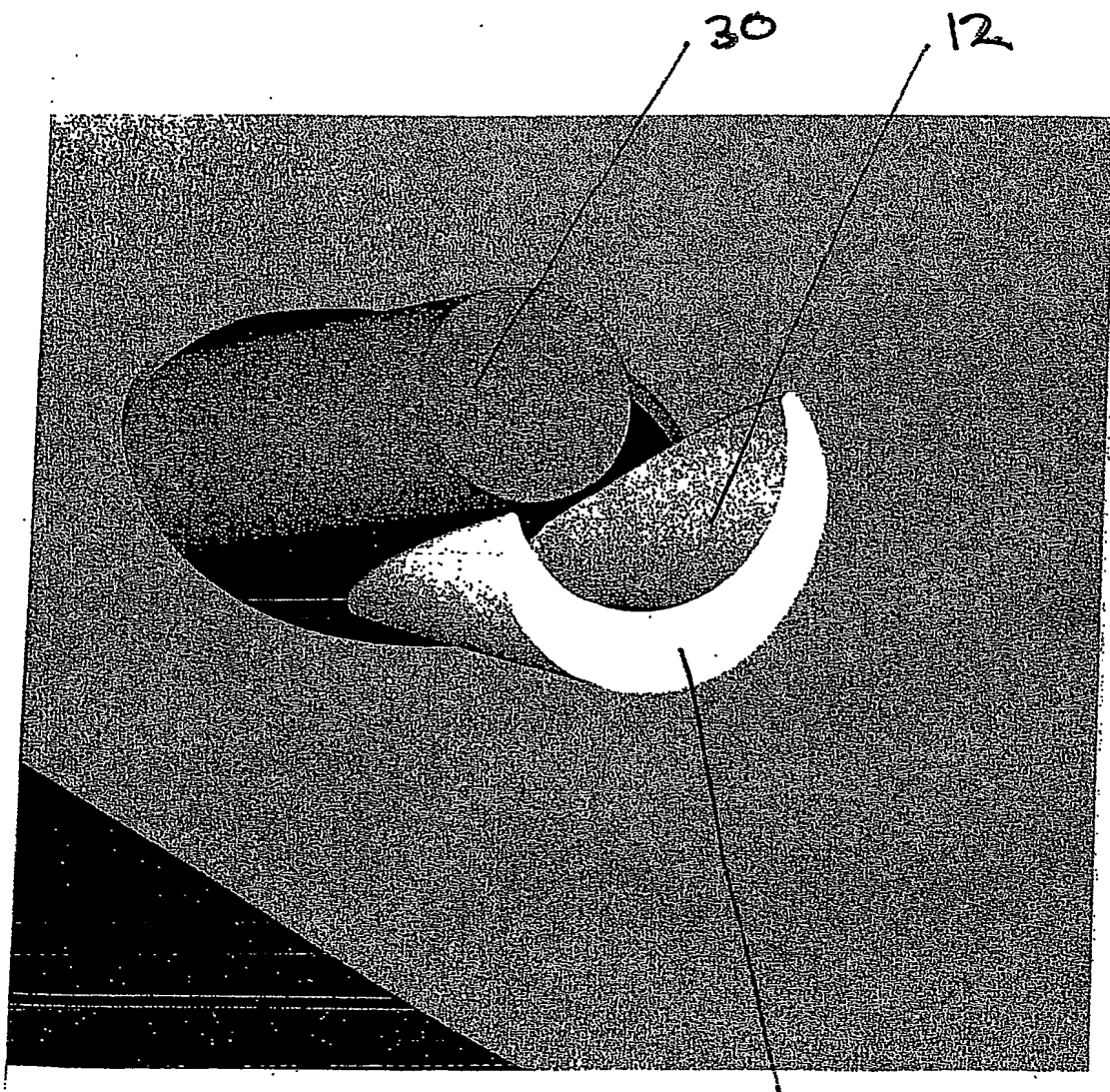


Figure 3

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Figure 4

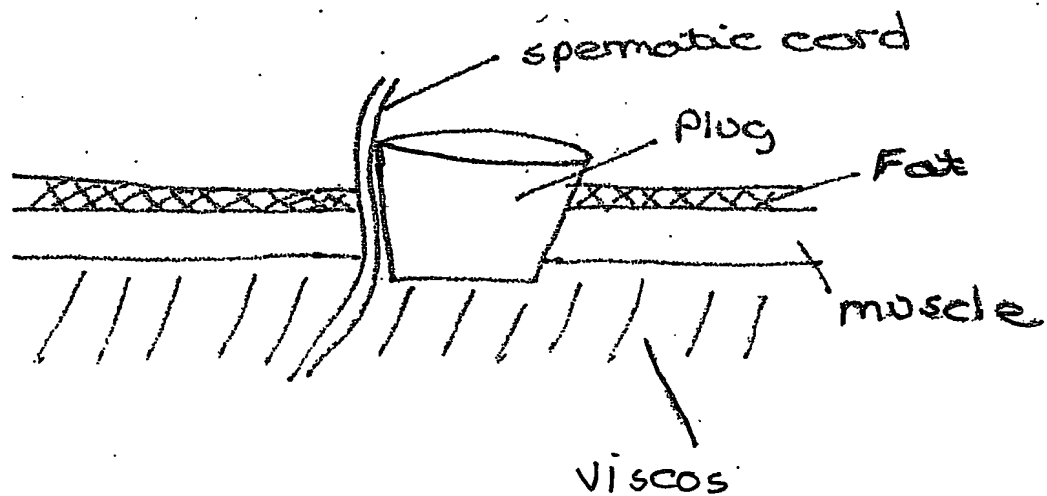
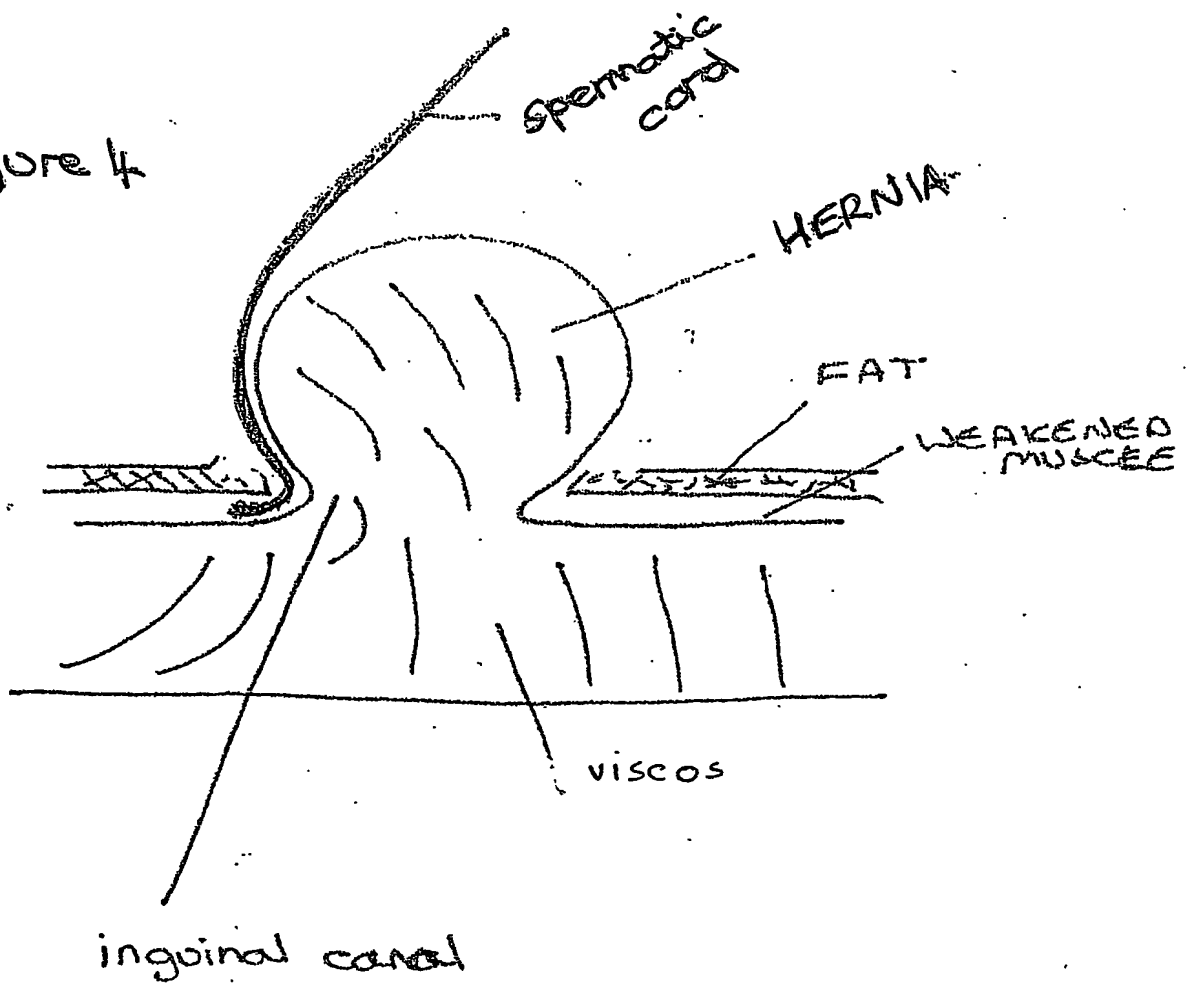


Figure 5

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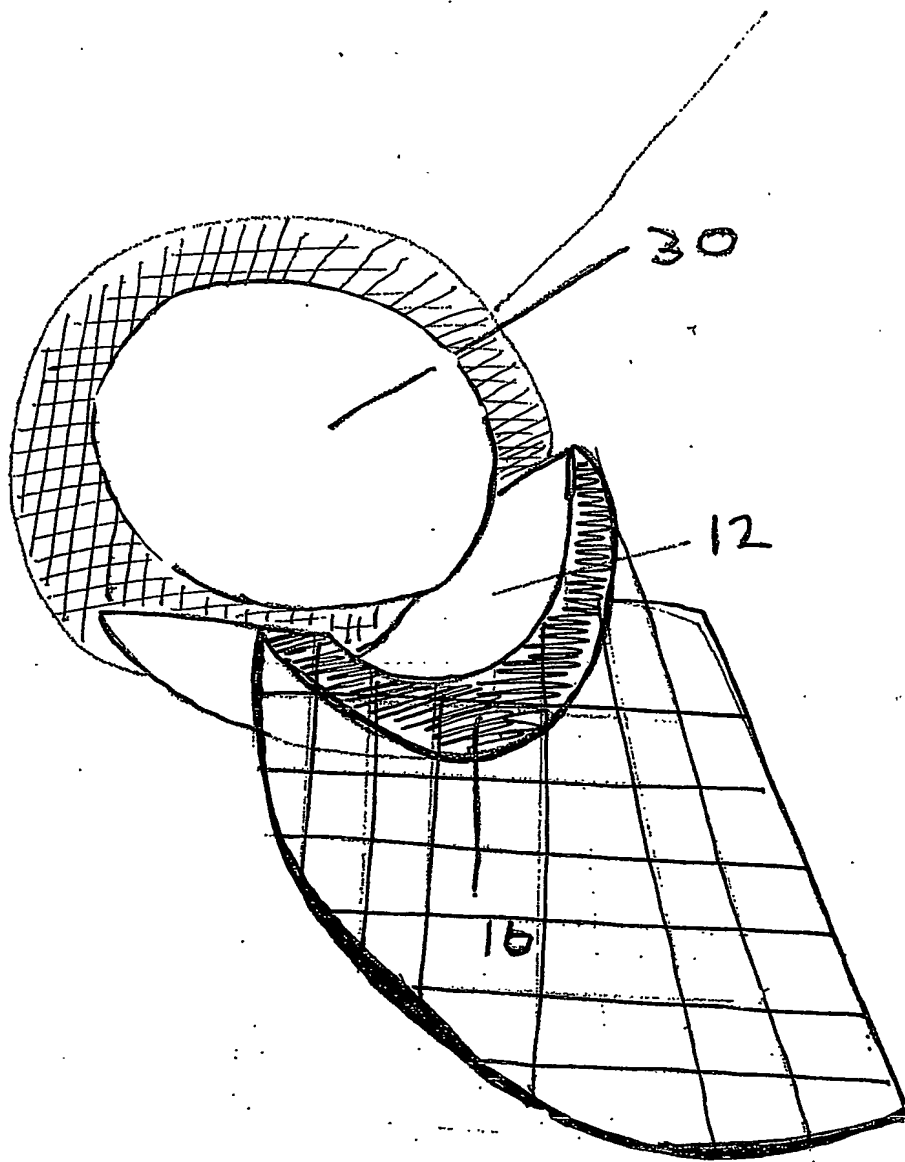


Figure 6

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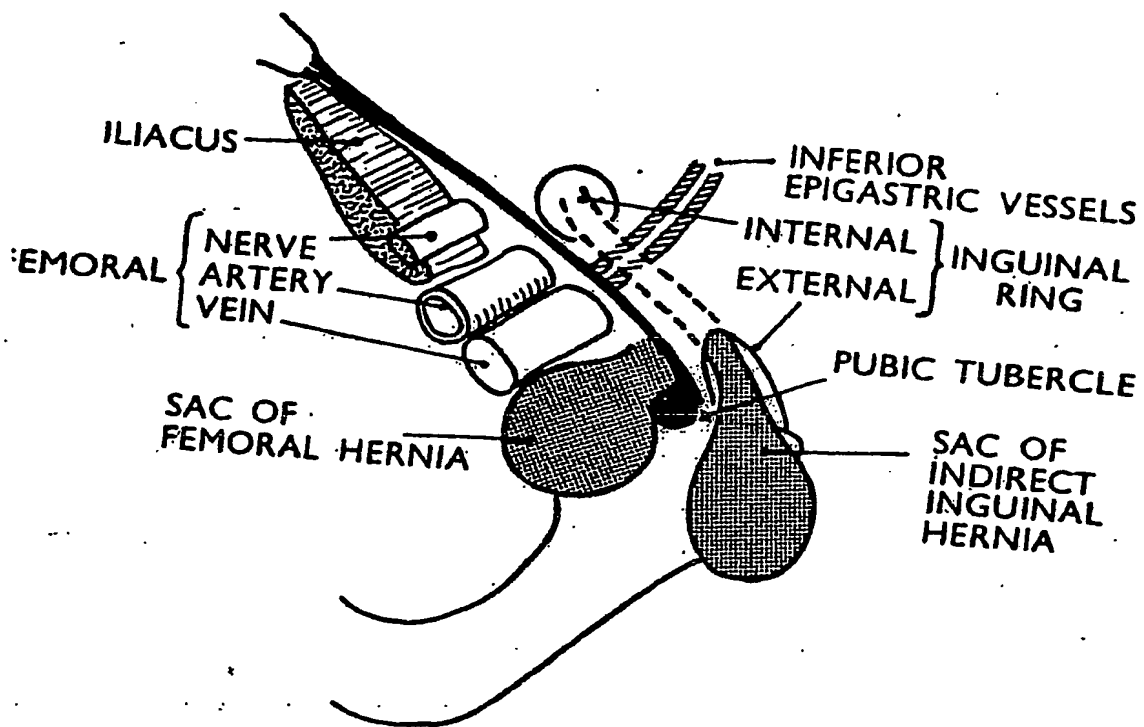


Figure 7

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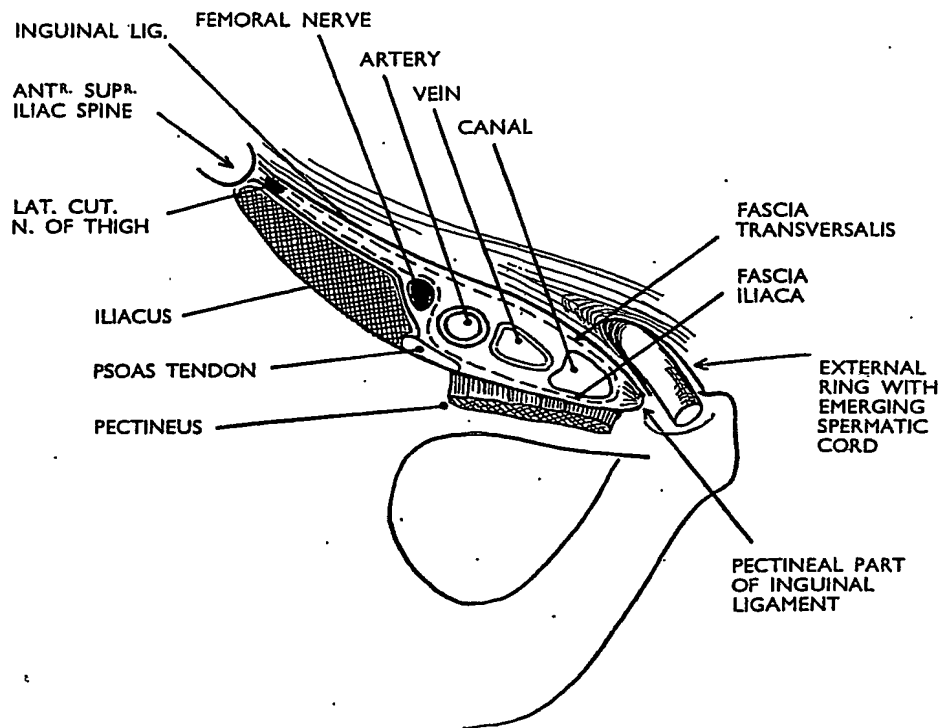
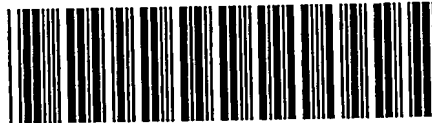


Figure 8

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